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K002632

VIII

SUMMARY
513(I)(3)(A)

Description of Device: The O2-ATOR™ is a topical oxygen chamber used as a stand alone or adjunctive modality in treating non-healing wounds. It is composed of a rigid plastic container that is fitted with a tube to accept O2 and a pressure relief valve that allows 22 mm of Hg. Pressure to remain inside the chamber. A pressure membrane on one end of the device allows the extremity to be placed inside a **disposable** plastic bag, then into the device thus ensuring proper sepsis control with each patient.

Intended Use: The O2-ATOR™ was designed to provide topical hyperbaric oxygen to open chronic wounds such skin ulcerations due to diabetes, venous stasis ulcers, post surgical infections, and gangrenous lesions. Other indications are decubitus ulcers, amputations/ infected stumps, skin grafts, burns and frostbite.

Comparison to Similar Devices: The O2-ATOR™ is quite similar in theory to the Oxycure Boot, K840817, Hospitak, Inc. 4/25/1984 and the Topical Hyperbaric Oxygen Chamber, K81593, Stevenson Industries 5/12/1986. All devices mentioned, including the O2-ATOR, are intended to deliver topical hyperbaric oxygen to open chronic wounds.

Non Clinical Testing: The integrity of the products and materials used to manufacture the O2-ATOR™ product are tested by suppliers of Adjunctive Therapeutics, Inc., to meet the specifications for the device. Testing is established by ASTM. Any material that comes into contact with the patient's body is in compliance with ISO biocompatibility. This is certified by the supplier of the materials to Adjunctive Therapeutics, Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 5 2001

Myron Z. Bernstein D.P.M.
Vice President
Adjunctive Therapeutics, Inc.
10 Scotch Mist Court
Potomac, Maryland 20854

Re: K002632
Trade Name: O2-ATOR™
Regulatory Class: III
Product Code: KPJ
Dated: August 18, 2000
Received: August 23, 2000

Dear Dr. Bernstein:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K002632

INDICATION OF USE

The O2-ATOR™ is specifically used in the treatment of acute or chronic wounds such as skin ulcerations due to diabetes, venous stasis post surgical infections, and gangrenous lesions. Other indications are Decubitus ulcers, Amputations/infected stumps, skin grafts, burns and Frostbite.

for Mark N Melhorn

(Division Sign-Off)
Division of General, Restorative Devices
510(k) Number K002632